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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
12/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

08/747,122

Applicant(s)

SELAWRY ET AL.

Examiner

Lora E. Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Applicant should note that the examiner for this case has changed since the last Office action.

The request filed on 6/15/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) was acceptable, and a CPA was established. On 8/29/01, the Office notified applicant by mail of a potential interference with another application and suspended action in this case. A status letter mailed by the Office on 7/11/02 advised applicants that the suspension was still in effect. On 3/17/03, the Office informed applicant that the suspension was withdrawn and the interference forthcoming.

Applicant's amendments filed 6/15/01 to claim 50 have been entered. Claims 47-49 were canceled in that reply. Only claim 50 remains pending in the current application and is being considered on its merits. Any objections or rejections of record that are not addressed below are withdrawn in light of the amendments and applicants' comments.

This Office action regards claim 50 as submitted 6/15/01. The Office regrets any inconvenience to applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Selawry et al. (1993, *Cell Transplantation* 2: 123-29; attached as reference U) taken in light of Xiaotao et al. (1995, *Journal of Pharmacology & Experimental Therapeutics* 274: 1192-98; attached as reference V).

Selawry teaches transplanting a Sertoli cell-enriched fraction (SEF) and pancreatic islets underneath the renal capsules of streptozotocin-treated rats. (Page 124, under "Animals," "Islet preparation," "Sertoli Cell-enriched Fraction Preparation," and "Transplantation of Rats.") Selawry teaches that rats so treated became normoglycemic and remained so for at least 200 days, with females even being able to bear litters of healthy pups. (Page 125, "Group 5.")

Xiaotao is cited solely as evidence that streptozotocin-treated rats are a model of type I diabetes mellitus. (Page 1995, column 1; page 1194, under "Results.")

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 19, 20, and 24-26 of U.S. Patent No. 5,725,854, which shares an inventor with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant claim overlaps the cited '854 claims.

Instant claim 50 is drawn to a method of treating type I diabetes mellitus in a mammal comprising transplanting Sertoli cells and pancreatic islet cells to a transplant site other than testes.

Claim 1 of the '854 patent is drawn to a method of treating a disease that results from a deficiency in a biological factor in a mammal comprising transplanting Sertoli

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cells and cells that produce the biological factor at an immunologically privileged site; claim 4 limits the disease to diabetes mellitus; claim 5 limits the cells to pancreatic islet cells; claim 7 requires that the administration be a transplantation.

Claim 19 of the '854 patent is drawn to a method of treating diabetes mellitus in a mammal comprising administering Sertoli cells and pancreatic islet cells to an immunologically privileged site; claims 24-26 are drawn to administration at sites other than testes.

Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 22, 23, 27-29, 47, and 49 of U.S. Patent No. 5,958,404, which shares an inventor with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant claim overlaps the cited '854 claims.

Instant claim 50 is drawn to a method of treating type I diabetes mellitus in a mammal comprising transplanting Sertoli cells and pancreatic islet cells to a transplant site other than testes.

Claim 1 of the '404 patent is drawn to a method of treating a disease that results from a deficiency in a biological factor in a mammal comprising transplanting Sertoli cells and cells that produce the biological factor; claim 4 limits the disease to diabetes mellitus; claim 5 limits the cells to pancreatic islet cells; claim 7 requires that the administration be a transplantation.

Claim 22 of the '404 patent is drawn to a method of treating diabetes mellitus in a mammal comprising administering Sertoli cells and pancreatic islet cells to an immunologically privileged site; claim 23 includes type I diabetes mellitus; claims 27-29 are drawn to administration at sites other than testes.

Claim 47 of the '404 patent is drawn to a method of treating a disease that results from a deficiency in a biological factor in a mammal comprising transplanting Sertoli cells and cells that produce the biological factor such that the cells are colocalized; claim 5 limits the cells to pancreatic islet cells.

Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 12, and 14 of U.S. Patent No. 6,149,907 in view of Selawry et al. (1993, *Cell Transplantation* 2: 123-29) and Xiaotao et al. (1995, *Journal of Pharmacology & Experimental Therapeutics* 274: 1192-98).

Instant claim 50 is drawn to a method of treating type I diabetes mellitus in a mammal comprising transplanting Sertoli cells and pancreatic islet cells to a transplant site other than testes.

Claim 11 of the '907 patent is drawn to a method of creating systemic tolerance to subsequent transplants comprising transplanting Sertoli cells prior to a transplant. Claim 12 permits that the transplanted cells are endocrine cells. Claim 14 permits that the Sertoli cells and endocrine cells are simultaneously transplanted.

Selawry teaches transplanting a Sertoli cell-enriched fraction (SEF) and pancreatic islets underneath the renal capsules of streptozotocin-treated rats. (Page

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124, under "Animals," "Islet preparation," "Sertoli Cell-enriched Fraction Preparation," and "Transplantation of Rats.") Selawry teaches that rats so treated became normoglycemic and remained so for at least 200 days, with females even being able to bear litters of healthy pups. (Page 125, "Group 5.")

Xiaotao is cited solely as evidence that streptozotocin-treated rats are a model of type I diabetes mellitus. (Page 1995, column 1; page 1194, under "Results.")

A person of ordinary skill in the art would have had a reasonable expectation of success in selecting the pancreatic islets of Selawry as the endocrine cells in the method of the '907 claims because Selawry teaches that the islets achieve endocrine function upon transplantation. The skilled artisan would have been motivated to select Selawry's islets in order to treat diabetes; Xiaotao teaches that Selawry's STZ-treated rats are a model of type I diabetes mellitus.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to select the islets of Selawry as the endocrine cells in the '907 patent's method because Selawry teaches that islets function as endocrine cells upon implantation and because Xiaotao suggests the desirability of transplanting islets to treat diabetic conditions.

The claim is not allowed. The claim is not free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the

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procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action in order to assist the examiner with double patenting analysis in the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651

